

ANTHRAX VACCINE

WHAT IS THE PUBLIC HEALTH PROBLEM?

The purpose of the Anthrax Vaccine Research Program (AVRP) is to conduct studies to determine factors associated with side effects from the vaccine. The goal is to discover whether the vaccine route can be changed and the number of doses can be reduced, while still providing protection against anthrax disease. The studies are also expected to provide more information on when a person becomes protected and how long the protection lasts. The current anthrax vaccine is injected just under the skin in a series of 6 doses over 18 months, followed by a booster dose given each year. One of the most common side effects of the anthrax vaccine is redness and swelling in the arm because the shot is given just under the skin instead of into the muscle. Some recent studies have shown that if the shot is given in the muscle, there may be less pain and swelling. It may also be possible to protect people with fewer than 6 shots. By doing this research, CDC hopes to reduce the number of side effects seen with the vaccine, while maintaining its effectiveness and increasing its acceptability.

WHAT HAS CDC ACCOMPLISHED?

In 1999, the U.S. Congress asked CDC to study the anthrax vaccine and the AVRP was developed. Since that time, CDC has designed studies that will determine:

- If it is possible to reduce some of the side effects by giving the shots in the muscle instead of under the skin;
- If the number of shots can be reduced;
- If the tests will show whether a person is protected;
- When protection occurs and how long it lasts.

This research will serve as the basis for development of newer anthrax vaccines. Research for these studies is being carried out in 6 different sites around the country. Some of the studies have already started. The protocol for the human clinical trial is undergoing review at this time at CDC, the Food and Drug Administration (FDA), and each of the 5 study sites where the human clinical trial will take place.

WHAT ARE THE NEXT STEPS?

This is a long-term set of studies that will take place over the next 4 to 5 years. Some of the studies are still in the planning and pre-study approval stages. It is anticipated that all the studies will begin early in 2002.

For more information on this and other CDC programs, visit www.cdc.gov/programs.

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